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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,169	11/16/2005	Reinhard Nubbemeyer	SCH-1947-02	3554
23599 7590 03/07/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER CHUI, MEI PING	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 03/07/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/522,169

Applicant(s)

NUBBEMEYER ET AL.

Examiner

MEI-PING CHUI

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 02/12/2007 and 01/24/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

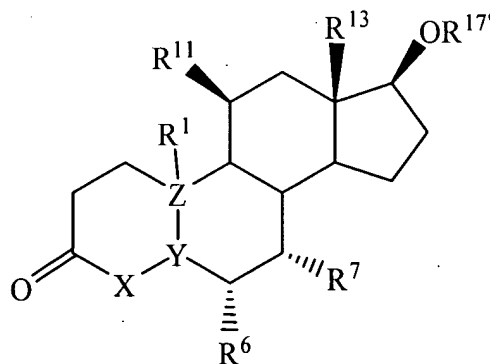
**DETAILED ACTION**

1. Claims 1-12 are pending in this application.

***Election of Species***

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

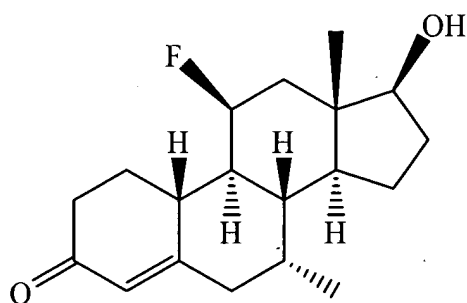
The species are each individual compound in the genus group of 11 $\beta$ -halogen steroid of formula I (see structure below), as recited in claim 1:



These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The technical feature linking the species is **the compound of 11 $\beta$ -halogen steroid of formula I**. Bohlmann et al. (WO 02/059139) teach a process of making an androgenic compound, namely 11 $\beta$ -fluoro-17 $\beta$ -hydroxy-7 $\alpha$ -methyl-estr-4-en-3-one, having the structure as below (Figure 1, compound I):



wherein its structure corresponds to the instantly claimed 11 $\beta$ -halogen steroid of formula I in the manner that:

- (i) X-Y-Z represents CH=C-C;
- (ii) R<sup>1</sup> = H;
- (iii) R<sup>6</sup> = H;
- (iv) R<sup>7</sup> = CH<sub>3</sub>;
- (v) R<sup>11</sup> = F;
- (vi) R<sup>13</sup> = CH<sub>3</sub>; and R<sup>17</sup> = H.

Therefore, in view of the teaching of 11 $\beta$ -fluoro-17 $\beta$ -hydroxy-7 $\alpha$ -methyl-estr-4-en-3-one compound by Bohlmann et al., this feature is not novel. Since the technical feature linking each instant invention is known, it does not constitute a special technical

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feature as defined by PCT Rule 13.2. The genus of an androgenic  $11\beta$ -halogen steroid of formula I lacks unity of invention, *a posteriori*.

Accordingly, the individual species of the androgenic  $11\beta$ -halogen steroid of formula I are not linked by the same or a corresponding special technical feature as to form a single general inventive concept.

4. Applicant is required, in reply to this action, to elect a single disclosed compound from the androgenic  $11\beta$ -halogen steroid of formula I, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The election of a species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### ***Joint Inventorship***

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. A telephone call was made to Mr. Zelano on 01/29/2008 to request an oral election to the above election of species.

## **DETAILED ACTION**

### ***Status of Action***

Applicant's election of species without traverse in the reply on 02/01/2008 is acknowledged. In response to the election of species, Applicants elected 11 $\beta$ -fluoro-17  $\beta$ -hydroxy-7 $\alpha$ -methyl-estr-4-en-3-one as the elected species of 11 $\beta$ -halogen steroid of formula I.

### ***Status of Claims***

Accordingly, claims 1-12 are presented for examination on the merits for patentability as they read upon the elected subject matter.

Comments: (1) For claims 1, 3 and 5, please inserts ---"A"--- before the term "composition", "pharmaceutical composition" and "male contraceptive". (2) For claims 2, 4 and 6-12, please insert ---"the"--- before the term "composition", "pharmaceutical composition" and "male contraceptive".

### ***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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**Claims 1-12** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

- (1) **Claim 1** is rejected because it recites the term “fluorinated derivatives” (see claim 1, line 4). The term “derivatives” is defined, according to Merriam-Webster’s Collegiate Dictionary (tenth Edition), as a chemical substance related structurally to another substance and theoretically derivable from it, or a substance that can be made from another substance (see page 311, derivative (n): meaning 4 and 5). However, the term “derivatives” is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree; it is unclear that the term “derivative” means a structural derivative or a functional derivative in relation to the fluorinated compound in the claim. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, and thus rendering the claim indefinite.

Claims 2-12 are rejected because they depend from claim 1 and thus incorporate its limitation.

- (2) **Claims 7, 10 and 11** are rejected because the claims recite the term “the organism of the user”. It is unclear that what the organism of the user is since the user has to be an organism.



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(3) **Claim 11** is rejected because it recites the term “transdermal system” in the claim.

However, this term “system” is not defined in the specification, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, it renders the claim indefinite.

(4) **Claims 7-12** are rejected for indefinite because the recited composition in claim 1

comprises both the androgenic compound, namely  $11\beta$ -fluoro- $17\beta$ -hydroxy- $7\alpha$ -methyl-estr-4-en-3-one, and the gestagen of the formula, as recited. However, claims 7 and 8 recite that the androgenic compound of formula I is formulated pharmaceutically. Likewise, claims 9-12 recite the gestagen is formulated pharmaceutically; it is unclear whether the pharmaceutical formulation requires the presence of both, the androgen and the gestagen, or requires the presence of only the androgen or only the gestagen. Thus, it renders the claims indefinite.

(5) **Claims 7, 9 and 10** are rejected because the term “extended period” is a relative

term which renders the claim indefinite. The term “extended period” is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, thus, rendering the claims indefinite.

Claim 11 is rejected because they depend from claim 10 and thus incorporate its limitation.

*Notes to the Applicants*

Claims 7 and 10 recite the phrase “can be” is an optional language and does not constitute a positive recitation in the claims. The subject matter of a properly construed claim is defined by the terms that limit its scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. Since the prior art and the invention as claimed comprise the same components, and are not structurally distinguishable. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Therefore, for the examination purpose, it is the examiner's position to interpret that the composition can be released over an extended period the same as the composition taught in the prior arts set forth above.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

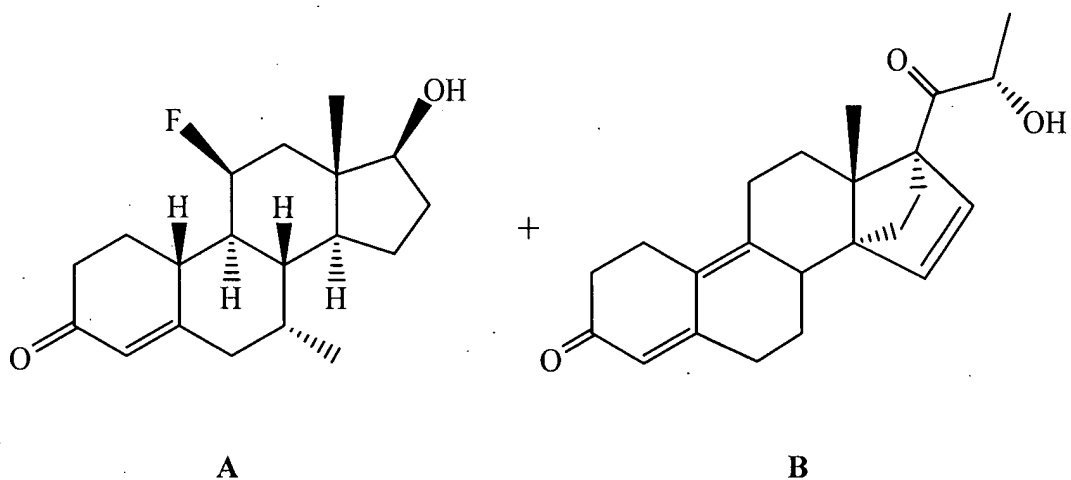
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohlmann et al. (WO 02/059139) in view of Krattenmacher et al. (Canadian Patent No. 2208605).**

### *Applicant Claims*

Applicants claim a composition comprising (i) an androgen, namely 11 $\beta$ -fluoro-17 $\beta$ -hydroxy-7 $\alpha$ -methyl-estr-4-en-3-one (structure **A** below), and (ii) a gestagen, namely (21S)-21-hydroxy-21-methyl-(4, 17-ethano-19-norpregna-4, 9, 15-trien-3, 20-dion (structure **B** below), in combination with (iii) a pharmaceutically compatible vehicle and/or adjuvants. Applicants also claim that the androgen compound is provided for oral administration, and the recited gestagen is formulated in transdermal system or is for oral administration:

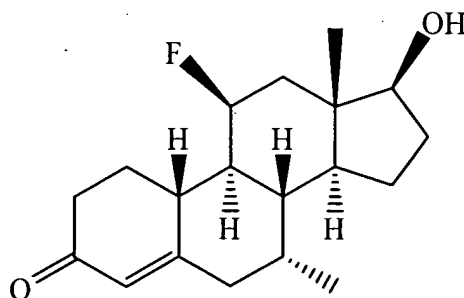
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***Determination of the scope and content of the prior art (MPEP 2141.01)***

Bohlmann et al. teach the use of an androgenic  $11\beta$ -halogen steroid for the production of pharmaceutical composition for male menopause or male birth control therapy (also known as male contraceptive) (page 1, paragraph 1, line 4-5 and paragraph 2, line 1-2).

Bohlmann et al. teach that the  $11\beta$ -halogen androgen steroid can be  $11\beta$ -fluoro- $17\beta$ -hydroxy- $7\alpha$ -methyl-estr-4-en-3-one (column 14, line 15-16 and Figure 1, compound I and structure below):



Bohlmann et al. also teach that the androgenic steroid, i.e. 11 $\beta$ -fluoro-17 $\beta$ -hydroxy-7 $\alpha$ -methyl-estr-4-en-3-one, can be prepared with at least one pharmaceutical compatible vehicle (page 11, line 19-21), and can be administered orally, parenterally or percutaneously (page 20, line 16 and page 20, line 16-18). It also can be used in combination with a progestogen to control male fertility (page 2, line 5-7 and page 13, line 3-4).

*Ascertainment of the difference between the prior art and the claims*  
(MPEP 2141.02)

Bohlmann et al. do not explicitly teach the progestogen, which is used in combination with the androgenic compound **A**, is the gestagen of compound **B** set forth above. However, the deficiency is cured by the teaching of Krattenmacher et al.

Krattenmacher et al. teach a 14, 17-C<sub>2</sub>-bridged steroid of formula (I) that has a good gestagen action. More specifically, Krattenmacher et al. teach the gestagen of formula (I) is (21S)-21-hydroxy-21-methyl-14, 17-ethano-19-norpregna-4, 9, 15-triene-3, 20-dione (page 7, line, which has the same structure as the compound **B**, as set forth above). Krattenmacher et al. also teach that the gestagen compound can be used alone or in combination with other steroids in preparations for contraception (page 9, line 19-21).

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Krattenmacher et al. further teach that the pharmaceutical formulation based on the gestagen can be used prepared with the pharmaceutical vehicles, diluents and can be administered orally or through a transdermal system or transdermally (page 11, line 8-9, 11, 14 and page 12, line 1-3).

***Finding of prima facie obviousness Rational and Motivation***  
***(MPEP 2142-2143)***

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teachings of Bohlmann et al. and Krattenmacher et al. to arrive at the instant claimed invention.

One of ordinary skill would have been motivated to utilize a gestagen, i.e. a progestogen of compound B, in combination with an androgenic compound A in preparation of male contraceptive with a reasonable expectation of success because a combination including an androgen and a progestogen is effective in reducing spermatogenesis and controlling male fertility, as taught by Bohlmann et al.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because the combined teachings of the prior art fairly suggests the instant claims, as evidenced by the references, especially in the absence of evidence to the contrary.

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### *Conclusion*

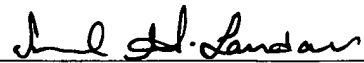
No claims are allowed.

### *Contact Information*

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Sharmila Gollamudi Landau", is positioned above a horizontal line.

Sharmila Gollamudi Landau

Primary Examiner

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